FORM PTO-1390 U.S. DEP (REV. 11-2000)	ARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTORNEY'S DOCKET NUMBER
TRANSMITTAL LETTER 7	O THE UNITED STATES	3868-0104P
DESIGNATED/ELECTE		U.S. APPLICATION NO. (If known, see 37 CFR 1.5)
CONCERNING A FILING	· ·	09/9\&\a100
INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/EP00/04970	Mayr 21 2000	Tuno 2 1000
TITLE OF INVENTION	May 31, 2000	June 2, 1999
	ANUFACTURING A PRODUCT FROM STR	IP TAPE, ESPECIALLY FOR
	OR ACTIVE SUBSTANCE-CONTAINING ONTAINERS OR SEALED-MARGIN BAGS	
APPLICANT(S) FOR DO/EO/US	or. HOPPMANN Hang-Dainer. SCHAI	FFD Wolfgang
Applicant herewith submits to the United States	Designated/Elected Office (DO/EO/US) the follow	
1. This is a FIRST submission of items conce		C 271
	omission of items concerning a filing under 35 U.S. examination procedures (35 U.S.C. 371(f)) at a	
	applicable time limit set in 35 U.S.C. 371(1)) at a	- ·
The US has been elected by the expirat	ion of 19 months from the priority date (Artic	• •
examination until the expiration of the The US has been elected by the expiration A copy of the International Application a. is transmitted herewith (require b. has been transmitted by the International Application c. is not required, as the application An English language translation of the company		
a. is transmitted herewith (require	d only if not transmitted by the International I	Bureau). WO 00/74618 A1
b. has been transmitted by the Inte	ernational Bureau.	
c. is not required, as the application	on was filed in the United States Receiving Of	fice (RO/US).
6. An English language translation of the	ne International Application as filed (35 U.S.C	C. 371(c)(2)).
a. is transmitted herewith.		
b. has been previously submitted	under 35 U.S.C. 154(d)(4)	
	rnational Application under PCT Article 19 (3	5 U.S.Ç. 371(c)(3)).
a are transmitted herewith (require	red only if not transmitted by the International	Bureau).
b. have been transmitted by the In	ternational Bureau.	
	the time limit for making such amendments ha	as NOT expired.
the state of the s	e amendments to the claims under PCT Articl	e 19 (35 U.S.C. 371(c)(3)).
9. An oath or declaration of the inventor		t d nominates
10. An English language translation of th (35 U.S.C. 371(c)(5)).	e annexes of the International Preliminary Ex	amination Report under PCT Article 36
Items 11. to 20. below concern document(s)	or information included:	
11. An Information Disclosure Statement (PCT/ISA/210) with 0 document(s).	under 37 CFR 1.97 and 1.98, Form PTO-144	9(s), and International Search Report
(ng. A separate cover sheet in compliance with	37 CFR 3.28 and 3.31 is included.
13. A FIRST preliminary amendment.		
14. A SECOND or SUBSEQUENT preli	minary amendment.	
15. A substitute specification.		
16. A change of power of attorney and/or		
[[- 	uence listing in accordance with PCT Rule 13	
l [national application under 35 U.S.C. 154(d)(4)	
	ge translation of the international application t	ander 35 U.S.C. 154(d)(4).
20. Other items or information:	notion Deport (DCT/IDE 4 /400)	
1.) International Preliminary Examin 2.) Three (3) Sheets of Formal Drawi		
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JC10 Ree'd PCT/FTO 3 0 NOV 2001

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21. The following fees	are submitted:				CAL	CULATIONS	PTO USE ONLY
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nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO							
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Independent Claims	2 - 3 =		0	X \$84.00	\$	0.00	
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	James M. Slattery, #28,380						
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PATENT 3868-0104P

IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicant:

NEULAND, Detlev et al.

Int'l. Appl. No.: PCT/EP00/04970

Appl. No.:

New

Group:

Filed:

November 30, 2001

Examiner:

For:

PROCESS AND DEVICE FOR

MANUFACTURING A PRODUCT FROM STRIP TAPE, ESPECIALLY FOR MANUFACTURING

A MEDICINAL AND/OR ACTIVE

SUBSTANCE-CONTAINING PRODUCT AS WELL AS FILLABLE CONTAINERS OR

SEALED-MARGIN BAGS

PRELIMINARY AMENDMENT

BOX PATENT APPLICATION

Assistant Commissioner for Patents Washington, DC 20231

November 30, 2001

Sir:

following Preliminary Amendments and Remarks respectfully submitted in connection with the above-identified application.

AMENDMENTS

IN THE SPECIFICATION:

Please amend the specification as follows:

Before line 1, insert -- This application is the national phase under 35 U.S.C. § 371 of PCT International Application No. PCT/EP00/04970 which has an International filing date of May 31, 2000, which designated the United States of America.--

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JMS/rem

3868-0104P

REMARKS

The specification has been amended to provide a crossreference to the previously filed International Application.

An early and favorable first action on the merits is earnestly solicited.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

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Process and device for manufacturing a product from strip tape, especially for manufacturing a medicinal and/or active substance-containing product as well as fillable containers or sealed-margin bags

The invention relates to a process for manufacturing a product from strip tape, especially a medicinal and/or active substance-containing product such as, for example, dermal or transdermal patches or another administration form, for example for oral application, as well as fillable containers or sealed-margin bags, in which process there is used as starting material a broad, active agent-containing web of material, for instance of sheet-like materials and, in particular, of active substance-containing sheeting or sheet-like active substance, said process comprising at least two of the following steps:

- separating the broad web of material into individual, narrow strips and, if necessary, winding the strips in individual coils or jointly twisting the strips.
- unwinding individual coils or pairs of coils, as required, and assembling at least two strips at a time to form a strip web, or unwinding the strip web wound up from individual strips.
- processing the web of material to form a product madeup of strip tape,
- performing final process steps as, for instance, manufacturing the final product, forming the final application form, laminating the carrier material, segregating, packaging etc.

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For manufacturing the above-mentioned products, strip tape consisting of a plurality of individual strips is used. This tape is made by separating a coilof the starting material into individual strips, said coil having a width resulting from the number of strips multiplied by the width of the strips plus edge trimming.

Typically, the resultant strips are wound on reels and are jointly unwound in the number as required and assembled to form webs of material having at least two layers.

10 The manufacture of the stock reels is very labourintensive, as is the winding and unwinding of the individual strips.

It is possible, here, that the material - which may be an active substance-containing material or a medicinal substance - is stretched impermissibly, with the unavoidable elongation of the material having a negative effect on the dosing accuracy of the medicinal substance.

It is the object of the present invention to provide a process and a device suitable for carrying out said process which overcome the aforementioned disadvantages, difficulties and technical limitations, and, in particular, enable the manufacture of a strip tape product, especially preferred an active substance-containing product, at reduced expenditure in respect of work and costs and without disadvantageous elongation of the material.

To achieve this object in a process of the kind mentioned at the outset, it is proposed according to the invention

- or that a roll of material with a broad web of the starting material be mounted, loosely rotatable, on a take-up mandrel,
- that the web of material be drawn, in its entire width and without subjecting the material to tensile stress, from the roll of material by means of a vacuum roll,

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or a device comprising two rolls, which unwinds the material gently from the material roll with one of the rolls simultaneously serving as a counter support to the cutting knifes; the material being separated in the process into individual strips in the negative pressure zone of the vacuum roll by rolling a multiple circular knife roll,

- that at the end of the negative pressure zone of the vacuum roll or of the pair of rolls, each strip be drawn from the said vacuum roll or pair of rolls and be introduced in a take-up channel and continuously conveyed therein my means of negative pressure,
- 15 that in the process each strip is turned on its way to the channel or through the channel by about 90°, and
 - that at the end of the channels the strips be led one upon the other, at least two at a time, and thereafter conveyed in a, preferably open, groove for further processing under completion to form the final product, to a conversion equipment where the products are finished.
- One embodiment of the process provides that for drawing the web of material and separating it into strips in cooperation with the multiple circular knife roll, there is used instead of a vacuum roll, a smooth stripping roll cooperating in a zone where the web of material travels around the roll with a pressure roll and a guide roll.

A device for the manufacture according to the present invention of a product from strip tape, especially of a medicinal and/or active substance-containing product such as, for example, a dermal or transdermal patch or another administration form, for example for oral application, as

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well as fillable containers or sealed-margin bags, especially for carrying out the process according to the invention,

5 is characterized in that:

- as a means for drawing off and separating the web of material a vacuum roll is provided, in whose web-travelling zone the web of material, held by the negative pressure, can be severed into individual strips in cooperation with the multiple circular knife roll,
- to each strip there is associated a vacuum conveyor channel which is designed such that each strip is turned on its way to the channel or through the channel by about 90°, and
- the ends of all the take-up channels 12 are brought together at one site to form a unit and that at that site there are provided guide means and transport means for the further transport to a conversion equipment.

One embodiment of the device according to the invention provides that as means for drawing the web of material and for transport during the separation into strips in cooperation with the multiple circular knife roll, there is provided instead of a vacuum roll, a smooth stripping roll arranged in a zone where the web of material travels around the roll and adapted to cooperate with a pressure roll and a guide roll.

The process according to the invention and the device provided for carrying out the same overcome the aforementioned disadvantages, difficulties and technical limitations of the prior art and, in particular, enable the manufacture of medicinal and/or active substance-containing

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products at reduced expenditure in terms of work and costs without disadvantageous elongation of the starting material.

Further details, features and advantages of this invention will become apparent from the following explanation of an embodiment example which is schematically illustrated in the figures.

The figures show:

- 0 Fig. 1: a side view of the device
 - Fig. 2: a plan view of the device according to Fig. 1
 - Fig. 3: a partial view of the device with vacuum transport channels disposed at the end of the device.
- 15 Fig. 4: a view of the device in which a smooth stripping roll is provided instead of a vacuum roll.

The part of the device represented in Fig. 1 shows rolls of material 1 with a web 2 of the starting material in a duplicate arrangement on both sides of a plane of symmetry x-x, said rolls 1 being mounted on take-up mandrels 3, as well as a duplicate arrangement of vacuum rolls 4, and circular knife rolls 5 rolling on said vacuum rolls 4 and the web of material 2 and having a plurality of parallelly disposed circular knifes.

The same device is shown in Fig. 2 in plan view, with rolls of material 1, mounting mandrel 3, the material web 2, which can be uncoiled, vacuum rolls 4, circular knife rolls 5, and strips of material 6 cut from the web 2 and running off the said circular knife rolls 5 at the end of the vacuum zone.

Fig. 3 shows, in part in side view and in part in plan 35 view, a vacuum roll 4. However, this may also be a stripping roll 8 aided by a guide roll 11, from which

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strips 6, cut by a circular knife roll (not shown), are transported in the width of the original web of material 2. For linear take-off of a plurality of strips 6 there are provided vacuum conveyor channels 12, each formed, for example, between two cover plates 13 and 14. Finally, Fig. 4 shows an alternative embodiment of the device wherein as means for drawing the material web 2 and for transport thereof during separation of the web of material in strips 6 in cooperation with a multiple circular knife roll 5 there is provided instead of a vacuum roll a smooth stripping roll 8 which is arranged in a zone in which the material web 2 travels around the roll and is adapted so as to cooperate with a pressure roll 10 and a guide roll 11.

The process and device are uncomplicated, reduce the expenditure of work and costs required heretofore, and enable the manufacture from strip tape of medicinal and/or active substance-containing products of various design, or of fillable containers or sealed-margin bags, while avoiding a disadvantageous elongation of the material, and, in particular, using a starting material in the form of sheet-like material, preferably a sheet-like active substance-containing administration form.

The present invention thus constitutes an optimal solution to the task presented at the outset.

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CLAIMS

1. Process for manufacturing a product from strip tape, in particular a medicinal and/or active substance-containing product such as, for example, a dermal or transdermal patch or another administration form, for example for oral application, as well as fillable containers or sealed-margin bags,

10 characterized in that

- a roll of material (1) with a broad web of material (2) is mounted, loosely rotatable, on a take-up mandrel (3),
- a web of material (2) is drawn, in its entire width and without subjecting the material to tensile stress, from the roll of material (1) by means of a vacuum roll (4), and is separated in the process into individual strips (6) in the negative pressure zone of the vacuum roll (4) by rolling a multiple circular knife roll (5),
- at the end of the negative pressure zone of the vacuum roll (4), each strip (6) is drawn from the said vacuum roll (4) and is introduced in a take-up channel (7) and continuously conveyed therein my means of negative pressure,
- in the process, each strip (6) is turned on its way to the channel or through the channel (7) by about 90°, and
- at the end of the channels (7) the strips (6) are led one upon the other, at least two at a time, and thereafter conveyed further in a, preferably open,

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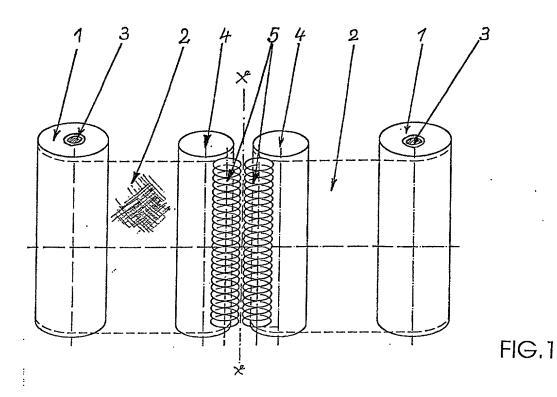
groove for further processing under completion to form the finished medicinal and/or active substancecontaining product or fillable containers or sealedmargin bags in a conversion equipment where the products are finished.

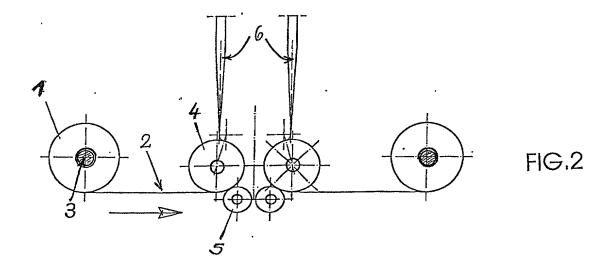
- 2. Process according to Claim 1, <u>characterized in that as</u> broad webs of material, sheet-like materials are used.
- 10 3. Process according to Claim 1, <u>characterized in</u> that as broad webs of material, active substance-containing sheet-like administration forms are used.
 - 4. Process according to Claim 1, characterized in that for drawing the web of material (2) and separating the same into strips (6) in cooperation with a multiple circular knife roll (5) there is used instead of a vacuum roll, a smooth stripping roll (8) which in a zone in which the material web (2) travels around the roll cooperates with a pressure roll (10) and a guide roll (11).
 - 5. Device for manufacturing a product from strip tape, especially a medicinal and/or active substance-containing product such as, for instance, a dermal or transdermal patch or another administration form, for example for oral application, as well as fillable containers or sealed-margin bags, especially for carrying out the process according to the invention,

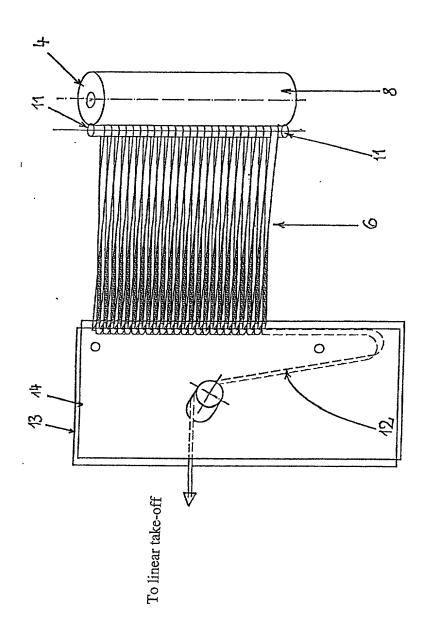
30 characterized in that:

- as a means for drawing off and separating the web of material (2) a vacuum roll (4) is provided, in whose web-travelling zone the web of material (2), held by the negative pressure, can be severed into individual strips

- (6) in cooperation with the multiple circular knife roll(5),
- to each strip (6) there is associated a vacuum conveyor channel (12) which is designed such that each strip (6) is turned on its way to the channel or through the channel (12) by about 90°, and
- the ends of all the take-up channels (12) are brought together at one site to form a unit and that at that site there are provided guide means and transport means for the further transport to a conversion equipment.
- 6. Device according to Claim 5, characterized in that as means for drawing the web of material (2) and for transport during the separation into strips (6) in cooperation with a multiple circular knife roll (5), there is provided instead of a vacuum roll, a smooth stripping roll (8) arranged in a zone where the web of material (2) travels around the roll and adapted to cooperate with a pressure roll (10) and a guide roll (11).







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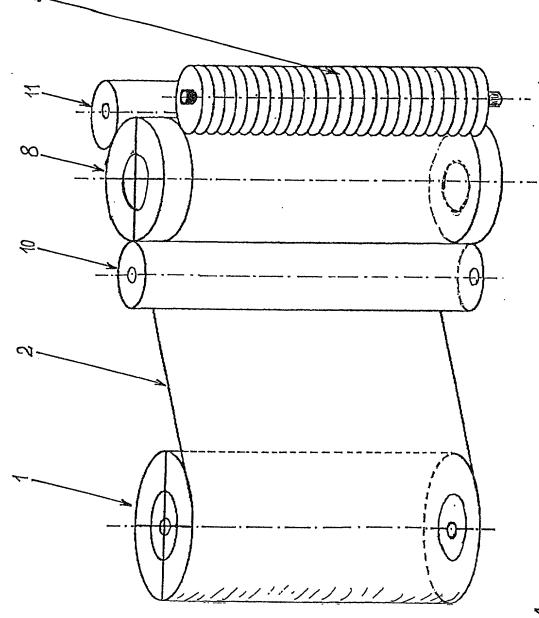


FIG.4

Attorney Docket No. 3868-0104P

(Status - patented, pending, abandoned)

BIRCH, STEWART, KOLASCH & BIRCH, LLP

PLEASE NOTE: YOU MUST COMPLETE THE FOLLOWING

Page 1 of 2 (Rev. 12/19/01)

P.O. Box 747 • Falls Church, Virginia 22040-0747 Telephone: (703) 205-8000 • Facsimile: (703) 205-8050

COMBINED DECLARATION AND POWER OF ATTORNEY FOR PATENT AND DESIGN APPLICATIONS

As a below named inventor, I hereby declare that: my residence, post office address and citizenship are as stated next to my name; that I verily believe that I am the original, first and sole inventor if only one inventor is named below) or an original, first and sont

•	inventor (if plural invention entitled:	entors are named below) of th	e subject matter which is cl	aimed and for which a patent	is sought on the
Insert Title:	PROCESS AND DEVIC MEDICINAL AND/OI MARCIN BAGS	E FOR MANUFACTURING A ACTIVE SUBSTANCE-CON	PRODUCT FROM STRIP T CAINING PRODUCT AS WE	APE, ESPECIALLY FOR MANUALL AS PILLABLE CONTAINE	JFACTURING A RS OR SEALED-
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Specification	and amended on			(if applica	ble) and/or
Attached:	the specification w	as filed on May 31, 2000			es PCT
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	amended on			(if	applicable)
	I acknowledge the Regulations, \$1.56.	Iment referred to above. duty to disclose information	which is material to paten	identified specification, includi- tability as defined in Title 37, ted States of America before my my or our invention thereof of a United States of America mo- ject of an inventor's certificate is a on an application filed by to this application, and that n ign to the United States of Ame (19(a)-(d) of any foreign application for patent or inventor's con-	Code of Federal
F	Prior Foreign Applic		•		y Claimed
Insert Priority Information:	199 25 339.0	GERMANY	June 2, 1999	🔯	
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	I hereby claim the benef	fit under Title 35, United States	Code, §119(e) of any United S	States provisional applications(s) listed below.
Insert Provisional Application(s): (if any)	(Application Number)		(Filing Date)		
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	I hereby claim the bene- insofar as the subject in application in the mann information which is mand between the filing date	fit under Title 35, United States natter of each of the claims of er provided by the first paragr aterial to the patentability as di of the prior application and the	Code, §120 of any United Str if this application is not dis aph of Title 35, United States fined in Title 37, Code of Fed national or PCT international	ites and/or PCT application(s) it closed in the prior United Sta Code, \$112, I acknowledge the deral Regulations, \$156 which it filling date of this application.	isted below and, tes and/or PCf duty to disclose pecame available
Insert Prior U.S Application(s): (if any)	(Application Number)	(Filing Date)		atus - patented, pending, aband	
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Attorney Docket No.

I hereby appoint the practitioners at CUSTOMER NO. 2292 as my attorneys or agents to prosecute this application and/or an international application based on this application and to transact all business in the United States Patent and Trademark Office connected therewith and in connection with the resulting patent based on instructions received from the entity who first sent the application papers to the practitioners, unless the inventor(s) or assignee provides said practitioners with a written notice to the confrary:

Send Correspondence to:

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P.O. Box 747 • Falls Church, Virginia 22040-0747

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

or sole inventor:		GIVEN NAME/FAMILY NAME	INVENTOR'S SIGNATURE	11	DATE*	
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		Residence (City, State & Country) Burghofstr. 123, 56566 Neuwied, Gen	- 4 /	German		
		MAILING ADDRESS (Complete Street Address including City, State & Country) Burghofstr. 123, 56566 Neuwied, Germany				
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